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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,625	03/21/2007	Derek O'Hagan	PP020407.0004	7269

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/554,625	**Applicant(s)** O'HAGAN ET AL.	
	Examiner Zachariah Lucas	**Art Unit** 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *7,9-11,16-20 and 22-26*.
   Claim(s) withdrawn from consideration: *21 and 27*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648

Continuation of 5. Applicant's reply has overcome the following rejection(s): Applicant's arguments in traversal of the obviousness type double patenting rejections over the claims of U.S. Patent 7329408 and over the claims of copending application 12/087330 are found persusaive. The rejection is therefore withdrawn. .

Continuation of 11. does NOT place the application in condition for allowance because: Applicant has presented three arguments in traversal of the obviousness rejection of record.
First, the applicant asserts that the arguments preveiously presented did not in fact attack the teachings of the references individually, but asserted that the teachings of the cited references as a whole do not recognize the use of an HCV E1E2 polynucleotide encoding residues 192-809 of the HCV polyprotein (corresponding to positions 20-637 of SEQ ID NO: 2 in the present application) with the subsequent administration of an HCV E1E2 polypeptide would be capable pf eliciting an immune response as claimed. The argument is noted. However, the assertion is not found perusaisve for the reasons of record (i.e. the combined teachings of the cited references do render such a method obvious, even if not actually teaching such a method, as indicated on page 15 of the action of July 2009).
The Applicant next asserts that the fact that the teachings of Ertl do not specifically address HCV should mitigate against reliance on the teachings of the reference in the rejection. The assertion is not found persuasive. The teachings of the reference indicate that the DNA prime and polypeptide boost strategy was known in the art. The teachings of the reference do not indicate that the strategy was limited to the use for any particular pathogen. Nor does the reference specifically indicate that the booster adminstration need be a mucosal administration in all situations. While the reference teaches the mucosal adminsration for the induction of a mucosal response against a particular subset (e.g. sexually transmitted) pathogens, the teachings of the reference as a whole indicate that the strategy, wherein the booster adminsitratin is not done mucosally, was recognized in the art as a means for inducing immune responses generally. See e.g., column 2, lines 30-34. Thus, the fact that the reference does not specifically address the induction of immune responses against HCV is not found persuasive in view of the indication of the gerenal applicability of the DNA prim/protein boost stategy in combination with the teachings of the additional cited references.
Finally, the Applicant presents arguments with respect to the fact that the Ertl reference specifically teaches the administration of the booster compositions via a mucosal route. As indicated above, while the reference is primarily directed to such booster administration, it was also noted above that this was in view of a desire to induce effective immune responses against sexual transmission via mucosal tissues. Nonethelesss, as was also indicated above, and previously, the reference also notes the general applicability of inducing immune responses using DNA prime/protein boost strategies wherein the protein antigen is adminsitered via other routes (e.g. wherein both the DNA and protein based compositions are administered systemically- column 2, supra). In view of such teachings, the fact that the reference also specifically teaches the induction of mucosal immune responses via mucosal adminsitration of the booster protein antigens is not found sufficent to teach away from, or otherwise render non-obvious the claimed methods.
Because the Ertl reference indicates that the mucosal adminstration is only required where a mucosal immune response is being required, and as the teachings of the reference indicates that the DNA prime/protein boost administration wherein the protein booster is not mucosally adminsitered would still have been an obviuos strategy for inducing an immune response, Applicant's arguments are not found persuasive even with respect to the claims as amended to require parenteral adminstration of the booster composition (i.e. administration through other than the alimentary canal). For these reasons and for the reasons of record, the rejection is maintained.

Applicant's arguments with respect to the rejection over the claims of copending application 10775964 in view of Houghto, Choo, and Ertl are noted. The arguments are not found persuasive for the reasons indicated in the orignal statement of the rejection, esp. in the paragraph on page 18, of the action mailed on July 24, 2009. This rejection is therefore maintained for the reasons of record.

Applicant's statement that they will consider the submission of a terminal disclaimer with respect to the copending application is not a sufficient basis on which to withdraw the rejection. The rejection is therefore maintained.

Applicant's arguments with respect to the rejection over the claims of the copending application 11653792 are noted, but are not found persuasive. While the indepentent claims of the copending application have been amended to specifically require the presence of HIV antigens, the dependent claims indicate that additional antigens, such as flaviviral (including HCV) antigens may be encoded by the vector of those claims. See e.g., claim 33. Thus, the copending claims do still read on overlapping subject matter with the present claims, wherein such subject matter would represent an obviuos variation of the copending claims. The rejection is therefore maintained.

Applicant's arguments with respect to the rejection over the claims of copending application 12231351 are noted. However, the claims of the copending application, while requiring the presence of a different set of protein antigens with the polynucleotide encoding the HCV E1E2 antigens, do not exclude the additional booster administration of the E1E2 polypeptides as suggested by the cited secondary references. The rejection is therefore maintained for the reasons of record.

Applicant's arguments with respect to the rejections over the claims of U.S. Patents 6,884,435 and 6,753,015 in view of the indicated secondary references are noted. The differences between the present claims and those of the indicated patents are noted and have been considered. However, they are not found persuasive in view of the teachings of the secondary references. The rejections are therefore maintained.